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Annual Summary Report for Award # DAMD17-99-1-9435
Dione Farria, MD, MPH
July, 1, 1999 to June 30, 2000

Introduction

The previous author, Peter Shile, M.D., is no longer with this Institution and no documentation of his work is accessible. Due to specific project requirements, his Statement of Work could not be continued under different authorship. A Statement of Work was submitted and approved for Dione Farria, M.D., who has also replaced Dr. Shile as a Breast Imaging Radiologist. The project was officially transferred on June 1, 2000 to Dr. Farria.

Purpose: 1. To obtain practical experience with patient outreach and educational program development for breast imaging and breast cancer patients.
2. To further develop public health research skills by conducting a series of small projects in the field of breast imaging, with an emphasis on the educational needs of underserved women.

Scope: The Statement of Work is a series of pilot studies addressing information needs and educational issues for women with breast disease. In addition to providing valuable experience, the projects will help generate hypotheses and data for larger studies in the future. The Statement of Work also includes opportunities to acquire skills in developing patient educational materials, both in the classroom setting and by participating in projects.

Body

Project: Breast Cancer: Dealing with the Diagnosis

This educational project involves the development of a factual handbook and a video for low literacy minority St. Louis women, who are recently diagnosed with breast cancer. Currently, the handbook and video projects are proceeding on schedule. As co-director, I have been actively involved in the research and development phase of this project. For the past few months, I have written

several chapters of the handbook and helped plan the overall format of the book. Currently, a complete draft of the text and illustrations have been compiled. All of task 1 objectives have been completed, except review with a literacy consultant, which is scheduled to occur in a few weeks.

All of Task 1 objectives have been completed for the video. The video will primarily deal with coping strategies for the newly breast cancer patient, with words of advice from survivors. The script has been developed with the assistance of Fleishman-Hillard Communications Firm. Several breast cancer survivors and local health care providers have been identified to participate in the video. Filming will begin in August.

Project: Improving Physician Communication with Breast Biopsy Patients

In addition to developing educational materials, I was recently awarded an Alvin J. Siteman Cancer Research Development Award. As principal investigator, this award complements the Department of Defense Award, by providing non-salary funding for the first year of a two-year project (see Tasks 5 and 7). The purpose of this project is to determine the relationship between the informed consent process, the timing of the breast biopsy, and psychosocial outcomes.

The project has two parts. The first phase of the project is the development of an educational intervention (flip chart) for physicians to use in the clinic setting when discussing breast biopsy or breast cancer treatment options with patients. The flip chart will primarily include diagrams and photographs with limited text, to increase the utility of the tool for low literacy women. The second year of the project is a randomized controlled trial. We will evaluate the effect of using the educational intervention on the validity of the informed consent process, patient anxiety, and patient satisfaction with the overall biopsy experience. We will also evaluate how these outcomes vary with the timing of the biopsy procedure. (See attached proposal summary.) Currently, I am in the process of obtaining IRB approval for this project.

Key Research Accomplishments

Alvin J. Siteman Cancer Center Research Development Award ($25,000)- *Evaluating the Effect of Informed Consent and Procedure Scheduling on Biopsy Patient Outcomes* (6/1/00 to 5/31/01).

Reportable Outcomes

None to report at this time.

Conclusions

Task 1 has been completed. In the next several months, I will continue revising and editing the handbook and video with my colleagues (Task 2). I will also start developing the educational intervention tool (flip chart- Task 5) a few months ahead of the proposed DOD schedule.

References

None to report at this time.

Appendices

I. DOD Statement of Work

II. Siteman Cancer Center Grant Summary

Dione Farria, MD, MPH
Statement of Work: Education and Outreach for Breast Imaging and Breast Cancer Patients

Months 1-3 **Task 1**: *Breast Cancer: Dealing with the Diagnosis: Part 1 (Research and Development)*
This educational project is a cooperative effort of Barnes-Jewish Breast Health Center and Fleishman-Hillard International Communications Firm. The project involves the development of a free educational handbook and video for low literacy minority St. Louis women with a new diagnosis of breast cancer. I will function as co-director of this project.

a) Handbook research and development
   - Research existing materials
   - Develop text outline and overall format
   - Identify/ develop illustrations for use in manual
   - Write draft of text and revise with literacy consultant (approximately 20 pages at 6th to 8th grade reading level)

b) Video research and development
   - Research existing video materials
   - Meet with breast cancer survivors to identify key messages for video
   - Develop script outline and overall format (approximately 5-7 minutes)

Months 4-6 **Task 2:** *Breast Cancer: Dealing with the Diagnosis: Part 2 (Production)*

a) Handbook (Produce 1000 copies)
   - Revise and edit text and illustrations
   - Obtain feedback on draft from 5 representatives of target audience through one-on-one discussions
   - Obtain feedback on draft from advisory panel members (breast cancer survivors, surgeons, radiologists, psychologists, social workers)
   - Produce 1000 handbooks
   - Develop preliminary distribution and promotion plan

b) Video (Produce 300 copies)
   - Select narrator and speakers for video
   - Revise and edit script
   - Film video and edit as needed
   - Obtain feedback on draft from target audience and advisory panel
   - Develop preliminary distribution and promotion plan

Months 7-8 **Task 3**: *Breast Cancer: Dealing with the Diagnosis: Part 3 (Distribution and Assessment)*
   - Promotion of products
   - Distribution free of charge to local women and clinics
   - Assess satisfaction with products by interviewing 20-30 women (10-15 who used the video and 10-15 who used the handbook)

Months 6-8 **Task 4**: *Health Promotion Program Planning (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which introduce the discipline of health education, including needs assessment, program planning, implementation and evaluation.

Months 9-14 **Task 5**: *Improving Physician Communication with Breast Biopsy Patients: Phase I*
The first phase of this project is the development of an educational flip chart for physicians to use in the office setting when discussing breast biopsy and treatment options with patients.

a) Focus group testing of women who have had a breast biopsy and breast cancer survivors to guide the content of the flip chart
b) Develop outline and overall format
c) Identify/develop illustrations and photographs for use in flip chart
d) Obtain feedback from radiologists, breast cancer surgeons, and women who have had breast biopsies
e) Obtain IRB approval for Phase 2

Months 9-11 **Task 6**: *Health Promotion Program Evaluation (St. Louis University School of Public Health)*
I will attend 5 class sessions (total of 40 hours) which cover the principles and procedures used to evaluate health promotion and disease prevention programs.

Months 15-23 **Task 7:** *Improving Physician Communication with Breast Biopsy Patients: Phase 2*
The second phase is a randomized trial, which assesses the utility of the flip chart in radiologist-patient discussions about imaging-guided breast procedures. Using patient surveys of women having imaging-guided biopsies, I will assess the impact of the educational tool on the following outcomes: 1) patient anxiety; 2) fulfilled expectations of the biopsy; 3) basic understanding of the procedure; and 4) patient satisfaction with the procedure.

a) Develop survey instruments for three timepoints: baseline, after discussion of procedure, and after biopsy.
b) Pilot survey in sample of 10 women.
c) Survey approximately 100 women.

Months 24-27 **Task 8:** *Improving Physician Communication with Breast Biopsy Patients: Phase 3*

a) Data entry and programming
b) Data analysis using bivariate analysis and logistic regression
c) Manuscript preparation

Months 28-33 **Task 9:** *Mammography Screening Practices of High Risk African-American Women: Phase I (Survey design)* This project is an exploratory study to assess the information needs and mammography screening patterns of African-American women who have a family history of breast cancer.

a) Obtain IRB approval
b) Focus testing of three groups of women (women with no family history, women with weak family history, and women with strong family history of breast cancer) to guide survey design.
c) Develop survey to assess characteristics of 3 groups (evaluate anxiety regarding breast cancer, compliance with mammography screening guidelines, and knowledge about personal breast cancer risk)

Months 34-42 **Task 10**: *Mammography Screening Practices of High Risk African-American Women: Phase 2 (Data collection)*

a) Conduct pilot test of survey on 10 women
b) Conduct surveys
c) Data entry, programming, and analysis using multivariate regression
d) Manuscript preparation

Months 43- 48 **Task 11**: *Mammography Screening Practices of High Risk African-American Women: Phase 3(Tailored Educational Materials)*

a) Develop an educational pamphlet based on survey results which is tailored to African-American women who have a family history of breast cancer.
b) Distribute via African-American health clinics, support groups and organizations.

Note: If time permits, I will conduct a pilot study, entitled *Improving Afro-American Participation in Breast Imaging and Breast Cancer Clinical Trials.* This task will include:

a) Identify all breast cancer related clinical trials at Washington University Medical School. Obtain information on sample size, patient demographics, age and socioeconomic status.
b) Conduct 2 focus groups: one with African-American women who have participated in a clinical trial and one with African-American women who have refused participation in a clinical trial.
c) Based on focus group data, identify an educational intervention to increase African-American participation in clinical trials. Apply for funding to test new intervention.

The Alvin J. Siteman Cancer Center

Where Science and Hope Grow Together

May 22, 2000

Dione M. Farria, M.D.
Washington University School of Medicine
Department of Radiology
Box 8131

Dear Dr. Farria:

I am delighted to inform you that your application entitled, "Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes," was chosen to be awarded as one of the five 2000 Siteman Cancer Center Research Development Awards pending issues listed below. Also, included with this letter, is a summary of reviewer comments, "Synopsis of Critiques," for your consideration.

As noted in your application, the Protocol Review and Monitoring Committee (PRMC) approval as well as Human Studies Committee (HSC) approval of your project are pending. Due to this time delay, we will need to receive a revised timeline assuring that your project will still be completed during the funding period. Monies will not be made available until all approvals and revised timeline are submitted to the Siteman Cancer Center Research Administration Office. Please submit these to Andrea Brown, Suite 2306, Kingshighway Building, or Siteman Cancer Center, Campus Box 8100. Following receipt of approvals, this $25,000 award will be available and your office or business manager will be contacted. Any extension of the term of this award (June 1, 2000 through May 31, 2001) will not be granted due to PRMC/HCS delays.

It is expected that you will completely utilize the full amount of funding awarded during the one-year term of the award. All unexpended funds at the end of the term will be returned. Extensions or changes to the terms of the award (length of funding period and budget) will only be made in exceptional circumstances. Upon a successful progress report due April 1, 2001, your application will be eligible for another year's funding up to an additional $25,000, however you may request a second year of funding only if the first year's funding has been completely expended.

Sincerely,

D Wilson for D Moley

Jeffrey F. Moley, M.D.
Chairman, Research Development Committee

Enclosure

cc: Laura Spight
Michelle Oakley
SCC file

Campus Box 8100 • 660 South Euclid Avenue • St. Louis, Missouri 63110-1093 • Phone: (314) 747-0359 • FAX: (314) 454-5300

The Alvin J. Siteman Cancer Center
Research Development Awards
Application Face Sheet

Principal Investigator: Dione M. Farria, M.D., M.P.H.

Academic Title: Assistant Professor **Department** Radiology

Box # or Address: Box 8131

Phone: 454-7690 **Fax:** 454-5206 **email:** farriad@mir.wustl.edu

Project Title:

Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes

Abstract: *(Do not exceed this space)*

We will evaluate two quality of care issues related to breast core biopsy: the informed consent process and biopsy scheduling. Since image-guided core breast biopsies have only been in widespread use for several years, these quality of care issues have not yet been fully addressed. Currently, it is unclear if patients' pre-biopsy information needs are adequately met during the traditional informed consent process. In addition, we do not know how women's information needs vary with the timing of the breast biopsy or with patient demographics. The purpose of our pilot project is to determine the relationship between the informed consent process, the timing of the biopsy, and several patient outcomes.

Through a randomized controlled trial, we will evaluate the effect of using an educational intervention (a visual flip chart used by the physician when discussing the biopsy procedure) on the validity of the informed consent process, as measured by factual knowledge related to the biopsy. We will measure the effect of the timing of biopsy performance on patient satisfaction with the overall biopsy experience, including the patient's perceptions of either excessive coercion or unnecessary delay in the diagnostic evaluation. We will also measure the effects of the educational tool and the timing of the biopsy on patient anxiety related to the procedure and subjective understanding of the procedure.

The study population will include 125 women at BJC Breast Health Center who are recommended for an imaging-guided core biopsy, but have no prior history of breast cancer. Patients will be randomized into two groups: the intervention group who are exposed to the educational tool, and the control group who undergo the routine informed consent process. Each of these groups will be further randomized into 2 subgroups based on the timing of biopsy performance: a) breast biopsy the same day as the mammography work-up; or b) breast biopsy one week after the mammographic work-up. Interviews will be conducted at three times: 1) baseline, prior to informed consent; 2) after informed consent; and 3) immediately after the biopsy.

We will use ANCOVA to test for main and interaction effects of the interventions (educational tool, biopsy timing). We will use structural equation modeling to test the fit of the data to a model of relationships among the interventions, anxiety, patient satisfaction, factual knowledge, and subjective knowledge.

The Alvin J. Siteman Cancer Center

The proposed study is a two-year project, and the design, background, and specific aims presented in this application reflect the overall goals of the study. However, we are presently requesting funding for only the first year of the project.

A. Specific Aims

Specific Aims of the Pilot Project

Aim 1 We will evaluate the effect of using a visual educational tool on the validity of informed consent for breast biopsy, as measured by the patient's factual knowledge related to the biopsy.

Aim 2 We will evaluate the effect of the timing of breast biopsy performance on patient satisfaction with the overall biopsy experience, including the patient's perceptions of either excessive coercion or unnecessary delay in the diagnostic evaluation.

Aim 3 We will evaluate the effects of the educational tool and the timing of the biopsy on a) reducing patient anxiety related to the biopsy; b) enhancing patient satisfaction with the biopsy experience; and c) increasing self-reported (subjective) understanding of the procedure.

Aim 4 We will explore the relationships among the interventions, patient anxiety, factual knowledge, subjective understanding and satisfaction with the biopsy experience.

Primary Study Hypotheses for the Pilot Project

1. We expect the educational intervention to increase the validity of informed consent, as measured by an increase in the patient's factual knowledge related to the biopsy.
2. We expect women in the intervention group (exposed to educational tool during informed consent) to report lower anxiety scores related to the procedure, greater patient satisfaction, and greater subjective understanding of the procedure than women in the control group.
3. We expect women who have their biopsy the same day as the breast imaging workup to report less factual knowledge and subjective understanding than women who have their biopsy one-week after their work-up.
4. We expect patient preferences and satisfaction to vary with patient demographics, such as age, education, family history, and prior biopsy history. Due to lack of data in the scientific literature, we cannot generate specific hypotheses on the relationship between demographics and biopsy timing.

B. Significance to Cancer Research

In the United States, approximately 1.2 million breast biopsies are performed annually, including approximately 330,000 image-guided core biopsies.[1] These minimally invasive procedures, which include stereotactic and ultrasound-guided biopsies, are proven cost-effective alternatives to surgical biopsies.[2] Core biopsies have revolutionized patient care by decreasing the time between detection and diagnosis, reducing the costs and morbidity of breast biopsies, and decreasing the number open surgical procedures needed for both benign and malignant disease.[2,3] However, since image guided core biopsies have been in widespread clinical use for less than a decade, some quality of care issues have not been fully addressed:

1) *Patient information needs*. Currently, it is unclear if patients' pre-biopsy information needs are adequately met by the standard informed consent process.
2) *Patient anxiety*. Although studies have shown a correlation between a patient's lack of understanding of a breast biopsy procedure and higher reported anxiety levels, no interventions have been tested to increase patient understanding and decrease anxiety related to the procedure.[4,5]

3) *Appropriate timing of procedures.*. There are wide variations in the timing of breast biopsies. Some facilities advocate same-day diagnosis, where a woman can receive her diagnostic breast imaging work-up and core biopsy all within several hours. At other facilities, patients wait longer periods, ranging from a few days to several weeks, to obtain a biopsy after a mammographic abnormality is detected. The impact of the timing of the breast biopsy on patient anxiety, satisfaction, and understanding of the procedure has not been studied. Furthermore, we do not know if the information needs for women in the same day diagnosis group differ from women who obtain their biopsy on a later visit.

This project will provide valuable information on the breast biopsy experience from the patient's perspective, assess the validity of the current informed consent process, and evaluate the effects of biopsy scheduling on patient outcomes. In addition, the data from this study will be valuable in developing a conceptual model to better understand the relationships between key aspects of clinical management (biopsy scheduling, informed consent) and breast biopsy patient outcomes (anxiety, satisfaction, knowledge). This preliminary theoretical framework may be relevant in other cancer patient populations as well. In addition, this study will provide a practical educational tool, which will facilitate doctor-patient communication in the breast clinic setting.

Cancer Center Collaborations

This project will be a collaborative effort of the Barnes-Jewish Breast Health Center and the Psychosocial Core of the Alvin J. Siteman Cancer Center. Mark Walker, PhD is a member of the Psychosocial Core, who will serve as co-investigator on this project. He is a psychologist in the Division of Health Behavior Research, who will play an active role in research design, survey instrument development, and statistical data analyses. The Health Communication Research Laboratory of St. Louis University School of Public Health, a component of the Psychosocial Core, will develop the educational intervention for use in this study. This group will be responsible for graphics, photo shoots, design and production of the educational tool, under the guidance of the study principal and co-investigators.

C. Background and Preliminary Investigations

Informed Consent

For most procedures, informed consent is obtained during an unstructured verbal encounter between the provider and the patient, with a written document requiring the patient's signature. This traditional method of informed consent has been studied for some procedures. These studies have shown relatively poor understanding of the proposed procedure. Olver et al[6] interviewed 100 patients having chemotherapy after obtaining informed consent. Only 34 patients understood the purpose of the written informed consent document; and 26 did not know the goal of their therapy. Only one patient considered the written document a major source of information about the procedure. In Montgomery's study, 25% of patients could not recall being told side effects during the consent process for radiotherapy; 28% were unhappy with the amount of information offered prior to the procedure.[7] Currently, there are no studies which assess whether the breast biopsy patient receives adequate information during informed consent.

Although the results of 80% of breast biopsies are benign, the procedure is associated with emotional distress.[8] Studies have shown that women awaiting excisional breast biopsies, experience anxiety levels exceeding those of patients undergoing other types of elective surgery.[9] For core breast biopsies, high anxiety levels are also reported. These anxiety levels appear to be related to the patient's

understanding of the planned procedure. In one study of 52 women, Maxwell[10] reported anxiety levels that were significantly higher than levels reported in general medical and surgical patients, similar to anxiety levels found in acute neuropsychiatric admission patients. Women experienced less pre-procedure anxiety if they were over 50 years old, married, or had a greater understanding of the core biopsy procedure. Handy et al[4] showed a statistically significant correlation between a patient's lack of understanding regarding the procedure and the patient's expected level of discomfort. Other studies have had similar results.

Based on a review of the literature, the educational intervention proposed in our study will likely increase the patient's knowledge about the procedure because: 1) More detailed information will be provided. Prior studies have shown that providing more detailed information during informed consent increases the patient's factual knowledge without increasing patient anxiety. Dawes et al,[11] based on a study of 190 patients scheduled for ENT surgery, reported that using a structured interview for informed consent increased factual knowledge, without increasing patient anxiety. Kerrigan[12] actually found a decrease in patient anxiety in patients who received detailed information about a planned inguinal hernia repair, suggesting some degree of reassurance in learning more before a procedure. 2). Luck[13], in a study of 150 subjects reported greater knowledge regarding the purpose of the procedure, procedural details and potential complications in patients exposed to the educational intervention. The treatment group also had less pre-procedural anxiety. Agre at al[14] had similar results. Like a video, the flipchart will add a visual component and more structure to the informed consent discussion. At least two studies showed an increase in factual knowledge by adding a video to the informed consent process for colonoscopy.

Timing of Breast Biopsies

The scientific literature has limited data on the effects of biopsy scheduling on patient outcomes. It is unclear if the current method of informed consent adequately prepares a patient for a rapid diagnostic work-up, such as a biopsy performed the same day as the mammographic examination. Allegheny General Hospital in Pittsburgh reports that 75% of their patients opt for a breast biopsy the same day as the mammogram, but a susbset of patients need more time.[15] For some women, a rapid diagnostic process may add anxiety, decrease the ability of the patient to assimilate information, and limit the time for the patient to generate needed support from family and friends. On the other hand, delays in obtaining a diagnosis may add stress for some women. The majority of breast cancer patients recall the diagnostic phase as the most stressful part of their experience, more stressful than the actual treatment or recovery. In a study of 238 women with benign biopsies, 58% recalled severe anxiety during the period from discovery to diagnosis.[16] More data is needed on the information needs of women in relation to the timing of diagnostic procedures. The proposed study will address some of these gaps in the literature, as well as generate pilot data on the effects of biopsy scheduling on key patient outcomes.

Donabedian Model of Quality Assessment

This study will add to the body of literature on quality of care issues in medicine. According to Donabedian,[17] quality of health care is defined in three areas- stucture (e.g. staffing, physical facility, etc), process (e.g., interpersonal communication of providers, technical skills, etc) and outcomes (e.g., patient morbidity, patient satisfaction, adherence to provider recommendations, etc). Based on Donabedian's framework for healthcare quality assessment, we will evaluate two process of care factors- the informed consent process and biopsy scheduling. We will evaluate how these two elements affect patient outcomes in three main areas of psychosocial effectiveness:[18]

a) cognitive- factual knowledge related to the procedure
b) attitudinal- patient satisfaction, subjective understanding
c) behavioral- anxiety.

D. Experimental Design and Methods

Project Design

We will conduct a randomized controlled trial. Subjects will be randomized into two main groups: the interventional group who are exposed to the educational tool and the control group, who are not exposed to the educational tool during informed consent. Each of these groups will be further randomized into 2 subgroups based on the timing of the biopsy: a) breast biopsy the same day as the mammography workup; and b) wait one week before having the breast biopsy.

Patients will be surveyed at three timepoints: prior to the informed consent, after the informed consent, and immediately after the biopsy. The interviews at each timepoint will take approximately 10 minutes, and will be administered by a trained research staff person. Four board-certified radiologists will conduct the informed consent discussions for both intervention and control groups. We will audiotape the informed consent discussions to assure standardization of content. Each outcome measure and the timing of data collection are outlined in the table in the appendix.

Eligible subjects are all women at BJC Breast Health Center who are recommended for an imaging-guided core biopsy (stereotactic or ultrasound-guided core biopsy). Women who have a prior history of breast cancer will be excluded from the study. For a sample size of 125 subjects, based on a 30% refusal rate, data collection will last 6-7 months. (The BJC Breast Health Center performs 350 image-guided core biopsies annually.)

Development of the Educational Intervention

The educational intervention is a flip chart, which will contain diagrams, photographs and text on laminated pages, mounted on a portable easel-like frame. The chart will include 30-40 pages with easy-to-read large print and colorful graphics, which will be beneficial for high and low literacy women and their family members. When the chart is not being used for consultations, it can fold up like a book and store on a bookshelf in an examination room. This flip chart will add a visual component to discussions during the informed consent, as well as help structure the discussion. Two focus groups and 20 to 30 patient interviews will add qualitative data, which will serve three purposes: 1) Guide the development of the educational tool used in this study; 2) Provide insight on the information needs of women who have breast biopsies, which will be helpful in designing the survey instruments; and 3) Provide feedback on the core biopsy experience, from the patient's perspective.

Data Analysis

Descriptive statistics (e.g., means, standard deviations) will be generated for all data. The primary analyses regarding each of the specific aims are outlined below:

Specific Aims 1-3: ANCOVA will be employed to test for main and interaction effects of the educational intervention and timing of the biopsy on post-consultation anxiety, post-consultation factual and subjective knowledge, and post-biopsy satisfaction. . Demographic variables, family history of breast cancer, baseline anxiety, baseline knowledge, and type of biopsy (ultrasound vs. stereotactic) will serve as potential covariates for these analyses.

Specific Aims 1-3: ANCOVA will be employed to test for main and interaction effects of the educational intervention and timing of the biopsy on post-consultation anxiety, post-consultation factual and subjective knowledge, and post-biopsy satisfaction. . Demographic variables, family history of breast cancer, baseline anxiety, baseline knowledge, and type of biopsy (ultrasound vs. stereotactic) will serve as potential covariates for these analyses.

Specific Aim 4: Structural equation modeling will be used to evaluate the fit of the data to a model of the relationships among treatment conditions, anxiety, factual knowledge, subjective understanding and post-biopsy satisfaction. The model (see figure 1) will be tested against a reduced model in which direct effects of treatment conditions on anxiety, satisfaction and subjective sense of understanding are fixed to zero.

For sample size considerations, we assumed a moderate effect size on the primary outcome variables of anxiety, objective and subjective knowledge, and satisfaction. In a simple test of the difference between means, this corresponds to an effect size *d* of .50, and is less than the effect sizes observed in other brief interventions aimed at reducing anxiety in a similar population.[19,20] With the projected sample size of 125, this would result in sample power of .79 for two-sided significance tests at the .05 level. However, this does not take into account the anticipated effects of the covariates, including demographic variables, type of biopsy, baseline anxiety and baseline knowledge. If these covariates account for just 10% of the variance of the outcome variable, we would have power of .97 to detect an increment of 10% in explained variance for two-sided significance tests at the .05 level.

For the structural equational models, Figure 1 includes 24 freely estimated parameters. According to Bentler,[21] a case to freely estimated parameter ratio of 5:1 may be adequate for testing structural models under normal distribution theory. Given the number of parameters in our model and our projected sample size of 125, we should have adequate power to evaluate the model under consideration (Figure 1).

Timeline

Months	1	2	3	4	5	6	7	8	9	10	11	12
Qualitative Data Collection:												
Focus Groups												
Provider Interviews												
Educational Intervention Design & Development												
Survey Design & Development												
Training of Interviewing Staff												
Pilot run - Sample of 10–15 Patients												
Months	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Data Collection												
Data Entry / Programming												
Data Analysis												

Future Aims

The pilot data generated from this study will provide a basis for future investigations, especially when applying for funding from NIH and other extramural sources. Three possible future investigations are outlined below: 1) In this era when cost containment is receiving increasing attention, this study may lead to a larger study, which explores alternative methods for delivering pre-procedural information to patients. For example, computer technology or a non-physician provider may deliver the factual content of our educational tool in a more cost-effective manner. 2) The information we learn about improving the informed consent process from this study may be applicable to other clinical settings. 3) Our educational tool will be useful in a number of clinical and research

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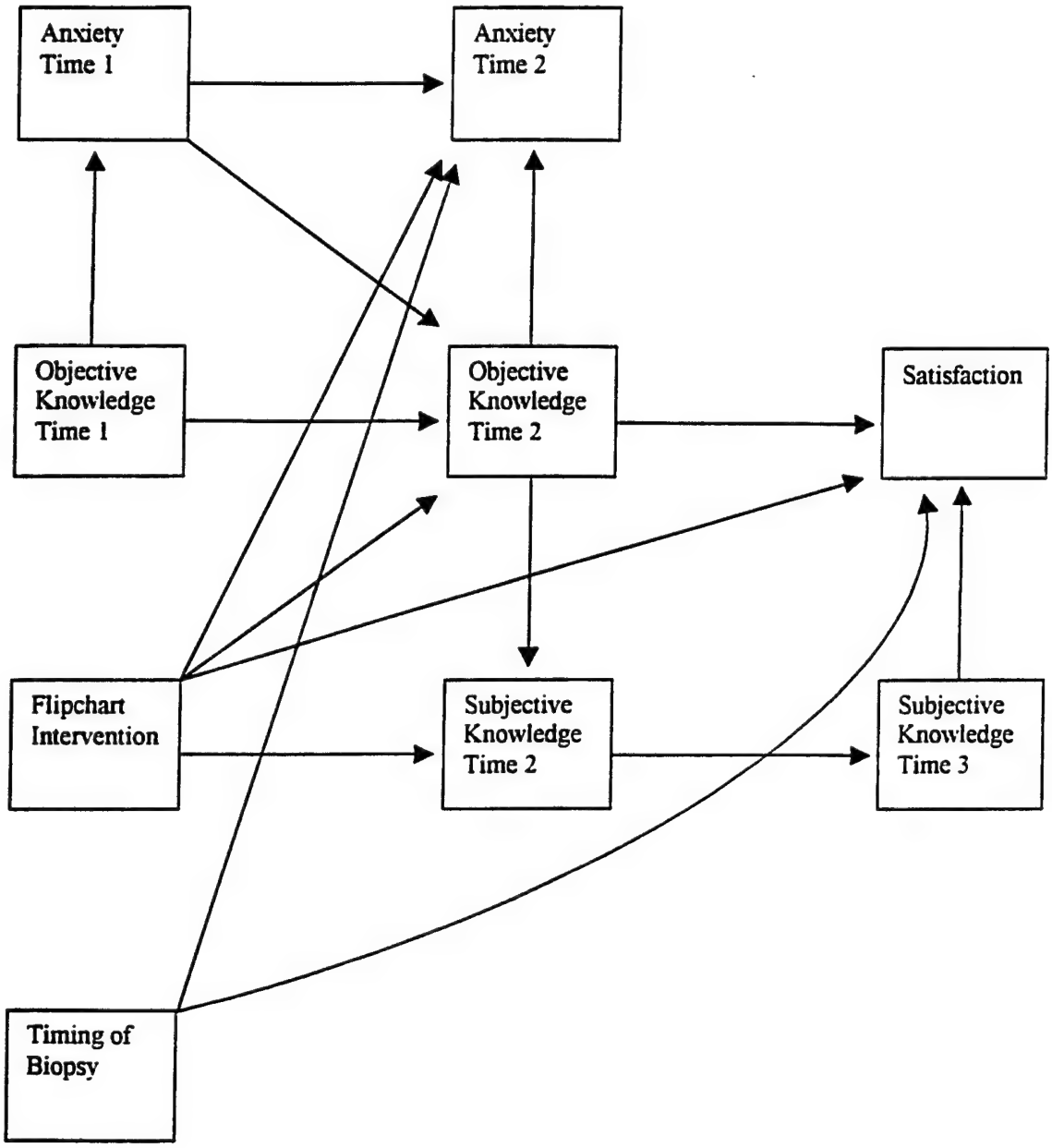
Table I

Outcome	*Measure*	*Timing of Measure*
Validity of informed consent	Will design a survey to obtain patient's factual knowledge of procedure.	1. Baseline- prior to consent 2. After informed consent
Patient anxiety related to procedure	a. Spielberger State Anxiety Inventory. b. One question rating anxiety on scale of 1-10.	1. Baseline 2. After informed consent 3. Immediately after procedure
Patient satisfaction with biopsy experience	We adapted a psychometrically valid survey, which is used in the BJC Breast Health Center.	Immediately after procedure
Subjective understanding of procedure	Will design a survey to assess patient's impression of their understanding of the procedure.	1. Baseline 2. After informed consent 3. Immediately after procedure

Figure 1. Relationship among treatment conditions, anxiety, objective knowledge, subjective knowledge, and patient satisfaction.



Demographic Information

1) What is your date of birth? _____

2) What is your marital status? (check one)

☐ Never married ☐ Divorced ☐ Separated

☐ Married ☐ Widowed ☐ Living Together

3) How many children do you have? _____

4) How far did you go in school? (Check highest grade level completed)

☐ <6 ☐ High School graduate ☐ Bachelor's degree

☐ 7-8 ☐ Some college ☐ Master's degree

☐ 9-11 ☐ AA degree ☐ Doctoral degree

5) What is your race or ethnic background

☐ Caucasian ☐ Hispanic ☐ Native American

☐ African American ☐ Asian American ☐ Other _____

6) What is your current employment status?

☐ Employed ☐ Retired

☐ Unemployed ☐ On medical leave

If employed, how many hours per week do you work? _____

7) What is your approximate annual family income? (thousands of dollars)

☐ <10 ☐ 20-30 ☐ 40-50 ☐ 60-70 ☐ 80-90 ☐ >100

☐ 10-20 ☐ 30-40 ☐ 50-60 ☐ 70-80 ☐ 90-100

8) What is your religious affiliation? _____

9) Have you had a breast biopsy before? ☐ Yes ☐ No

If so, what kind was it? _____

10) How long since you learned you needed a biopsy? (# of days) _____

11) Do you have any other serious or chronic illnesses for which you are receiving treatment? ☐Yes ☐ No If so, please specify _____

Barnes-Jewish Breast Health Center

Name_____ **HSC Protocol No.**_____
Subject Study No._____ **DOB**_____ **Registering MD**_____
Date_____

Subjective Understanding and Expectations (Administered at Baseline)

Please circle the number that describes how much you agree with each of the following statements, from 1- Strongly disagree to 5- Strongly agree.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I know what to expect with my biopsy.	1	2	3	4	5
2. I understand what I need to know before having my biopsy.	1	2	3	4	5
3. .I am ready to have my biopsy.	1	2	3	4	5
4. I need more information before my biopsy.	1	2	3	4	5
5. I have enough information to make any decisions I need to make about my biopsy.	1	2	3	4	5
6. I know what to expect regarding my biopsy.	1	2	3	4	5
7. I want to hurry and get the biopsy over with.	1	2	3	4	5
8. I need more time to think about things before my biopsy.	1	2	3	4	5

Self-Evaluation Questionnaire
STAI Form Y-1

Please provide the following information:

Name_____Date_____S_____

Age_____Gender (Circle) M F T_____

Directions:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	somewhat	moderately so	very much so
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Factual Questionnaire (Baseline)

1. Which of the following choices is a risk of this breast biopsy procedure?
   A. Blood clots
   B. Bleeding
   C. Diarrhea
   D. Deformity of the breast

2. After this breast biopsy, how long will you need to stay in bed?
   A. 24 hours
   B. 3 days
   C. 1 week
   D. I will not need to stay in bed.

3. During this biopsy procedure, what will the doctor remove?.
   A. A few tiny cells
   B. Small thin pieces of tissue
   C. Fluid only
   D. The entire lesion

4. What type of anesthesia, if any, is used for this biopsy?
   A. No anesthesia is used
   B. Local anesthesia
   C. Valium
   D. General anesthesia

5. Because I am having this biopsy, I will definitely not need to have surgery at a later date.
   A. True
   B. False

Subjective Understanding and Expectations (Administered after Biopsy consent)

Please circle the number that describes how much you agree with each of the following statements, from 1- Strongly disagree to 5- Strongly disagree.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I do not know what to expect with my biopsy.	1	2	3	4	5
2. I understand what I need to know before having my biopsy.	1	2	3	4	5
3. .I am not ready to have my biopsy.	1	2	3	4	5
4. I need more information before my biopsy.	1	2	3	4	5
5. I have enough information to make any decisions I need to make about my biopsy.	1	2	3	4	5
6. I need more time to think about things before my biopsy.	1	2	3	4	5

Self-Evaluation Questionnaire
STAI Form Y-1

Please provide the following information:

Name_____Date_____S_____

Age_____Gender (Circle) M F T_____

Directions:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	somewhat	moderately so	very much so
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Factual Questionnaire (After Biopsy Consent)

1. Which of the following choices is a risk of this biopsy procedure?
   A. Blood clots
   B. Hot flashes
   C. Numbness and swelling of your arm
   D. Infection

2. When can you expect to get your biopsy results?
   A. Immediately after the biopsy
   B. In 4-6 hours
   C. In 2-4 days
   D. In 2-3 weeks

3. I will be able to resume normal activity right away.
   A True
   B False

4. For this biopsy, I will
   A. Lie on my back
   B. Lie on my stomach
   C. Stand
   D. Sit

5. What are other ways that you can have this lesion biopsied?
   A. Skin biopsy
   B. Surgical biopsy
   C. Blood test
   D. There are no other ways that I can have this lesion biopsied.

Subjective Understanding and Expectations (Administered After Procedure)

Please circle the number that describes how much you agree with each of the following statements, from 1- Strongly disagree to 5- Strongly disagree.

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I understood what I needed to know before having my biopsy.	1	2	3	4	5
2. I was ready to have my biopsy.	1	2	3	4	5
3. I needed more information before my biopsy.	1	2	3	4	5
4. I knew what to expect regarding my biopsy.	1	2	3	4	5
5. I felt rushed in the timing of breast biopsy.	1	2	3	4	5
6. I felt the timing of my biopsy was unduly delayed.	1	2	3	4	5
7. I needed more time to think about things before my biopsy.	1	2	3	4	5
8. I think it is better to have a biopsy the same day you learn that you need one.	1	2	3	4	5
9. I think it is better to wait a week after learning you need a biopsy to have one.	1	2	3	4	5

Name _____ **DOB**_____
Subject Study No._____
Date_____

Patient Satisfaction with Biopsy Experience (Administered After Procedure)

Please circle the number that describes how satisfied you are with your medical experience, from 1- Completely dissatisfied to 7–Completely satisfied.

How satisfied are you with:	**Completely Dissatisfied**	**Very Dissatisfied**	**Dissatisfied**	**Neutral**	**Satisfied**	**Very Satisfied**	**Completely Satisfied**
1. The personal attention you received.....	1	2	3	4	5	6	7
2. The usefulness of the information you received	1	2	3	4	5	6	7
3.The ability of health providers to answer your questions	1	2	3	4	5	6	7
4. The knowledge and skill of the health providers	1	2	3	4	5	6	7
5.The comfort of the physical environment.....	1	2	3	4	5	6	7
6.The length of time of your appointment.....	1	2	3	4	5	6	7
7. Your medical consultation prior to your biopsy.....	1	2	3	4	5	6	7
8. Your overall biopsy experience.....	1	2	3	4	5	6	7

9. How stressful was your biopsy experience?
___Not stressful at all
___A little stressful
___Moderately stressful
___Very stressful

Demographic Questions

1. Which of the following backgrounds describes you best? Are you:
Check all that apply.
___White, non-Hispanic
___Hispanic
___Black, African-American
___Asian or Pacific Islander
___Other. Please specify_____.
___Don't know

2. What is the highest grade or level of education that you have completed?
_____8th grade or less
_____Some high school
_____High school diploma or trade school
_____Some college
_____College degree
_____Graduate school
_____Don't know

Do you have any additional comments about your biopsy experience here today?_____
_____

REVISED TIMELINE FOR GRANT PROPOSAL:
Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes
Principal Investigator: Dione Farria, MD, MPH
Phone: 454-7690

Year 1

Months (2000-2001)	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May
Qualitative Data Collection:											
Provider Interviews	X	X									
Focus groups		X	X								
Educational Intervention Design & Development			X	X	X	X	X	X	X		
Survey Design and Development							X	X			
Training of interviewing staff									X		
Pilot run- sample of 10 to 15 patients										X	X

Year 2

Months	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May
Data Collection	X	X	X	X	X	X	X	X	X			
Data Entry			X	X	X	X	X	X	X	X		
Data Analysis											X	X